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Neusoft

510(k)

K121792

510（K） Summary

This 510(k) summary of Safety and Effectiveness information is submitted in accordance with the requirements of 21 CFR Part 807.92

General Information:

Trade Name:	NeuViz 64 Multi-slice CT Scanner System
Common Name:	CT Scanner
Classification Name:	21 CFR Part 892.1750 Computed Tomography X-ray System
Classification:	Class II
Performance Standard:	21 CFR Subchapter J, Federal Diagnostic X-ray Equipment Standard
Manufacture:	Neusoft Medical Systems Co., Ltd. No.16 Shiji Road, Hunnan Industrial Area, Shenyang, Liaoning, China, 110179
Distributor:	Neusoft Medical Systems Co., Ltd. No.16 Shiji Road, Hunnan Industrial Area, Shenyang, Liaoning, China, 110179
Submitter:	Contact : Tian Yuehui Title : Manager of Q&R Department Tel : 86-24-83660646 Fax : 86-24-83660563 E-Mail : tianyh@neusoft.com

Summary prepared :Sept.20, 2012

Safety and Effectiveness information

Intended Uses:

The NeuViz 64 Multi-Slice CT Scanner System can be used as a whole body computed tomography X-ray system featuring a continuously rotating X-ray tube and detector array. The acquired X-RAY transmission data is reconstructed by computer into cross-sectional images of the body from either the same axial plane taken at different angles or spiral planes taken at different angles.

Device Description:

The NeuViz 64 Multi-slice CT Scanner System is composed of a gantry, a patient couch, an operator console and includes image acquisition hardware and software, and associated accessories. It is designed to be a head and whole body X-ray computed tomography scanner which features a continuously rotating tube-detector system and functions according to the fan beam principle. The system software is an interactive program used for X-ray scan control, image reconstruction, and image archive/evaluation.

The NeuViz 64 Multi-slice CT Scanner System is of comparable type and substantially equivalent to the SIEMENS Sensation 64 CT system (K040665) and NeuViz 16 Multi-slice CT Scanner System(K092742).

The NeuViz 64 system consists of two variants:
- NeuViz 64i : Low configuration;
- NeuViz 64e: High configuration.

The differences are the capacity of Tube and High Voltage Generator, and relevant specification/performance.

Predicated Devices:

SIEMENS Sensation 64 CT system (K040665)
NeuViz 16 Multi-slice CT Scanner System(K092742)

Statement of Substantial Equivalence:

In the opinion of Neusoft Medical Systems Co., Ltd., the **NeuViz 64 system** is of comparable type and substantially equivalent to the **SIEMENS Sensation 64 CT system** (K040665) that complies with the same or equivalent standards and has the same intended uses. All of these systems use on-board high frequency High-Voltage generator to generate X-radiation from X-ray tube. The X-ray transmission data is detected by the Solid-State detector and is reconstructed by the computer which has an interactive user interface. Both of these devices produces two dimensional image and 3D image that can be filmed or electronically stored for future review.

The safety and effectiveness of the **NeuViz 64 system** was assured by adherence to Good Manufacturing Practices(GMP) 21CFR 820 and to International Standards ISO 13485:2003. The following quality assurance measures were applied to the development of the system:

Risk analysis is performed according to ISO 14971 standard and internal risk management procedure.

Software safety is assured by the company procedures that conform to accepted practices. Quality assurance procedures are adhered to, and meeting the specifications and functional requirements if demonstrated via testing.

Requirements are tracked and **design reviews** are implemented.

Verification and validation activities(including performance testing, safety testing and simulated use testing) are performed.

Electrical and Mechanical safety is assured by adherence to IEC 60601-1 Standards

Radiation safety is assured by compliance with 21 CFR, Subchapter J Performance standards

Dose check is assured by compliance with NEMA XR25 Dose check standard

Clinical testing: Sample clinical images were obtained from 260 subjects at 2 sites. Radiologist assessed the diagnostic quality of the images, and the conclusion is that the images are of diagnostic quality and can meet the clinical requirements.

Based on the above considerations, it is Neusoft's opinion that **NeuViz 64 system** is substantially equivalent in safety and effectiveness to the predicate device: **SIEMENS Sensation 64 CT system** (K040665).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

Neusoft Medical Systems Co., LTD.
% Mr. Charles Mack
Correspondent
IRC USA
77325 Joyce Way
Echo, OREGON 97826

November 16, 2012

Re: K121792
Trade/Device Name: NeuViz 64 Multi-Slice CT Scanner System
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed Tomography X-ray System
Regulatory Class: II
Product Code: JAK
Dated: October 2, 2012
Received: October 2, 2012

Dear Mr. Mack:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely Yours,

Michael D. O'Hara

Janine M. Morris
Director
Division of Radiological Devices
Office of In Vitro Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K121792

Device Name: NeuViz 64 Multi-Slice CT Scanner System

Indications for Use:

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Prescription Use __Yes___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Michael D. O'Hara

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health

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